



Paul E. Helliker
Director

Department of Pesticide Regulation



Gray Davis
Governor
Winston H. Hickox
Secretary, California
Environmental
Protection Agency

MEMORANDUM

TO: Tobi Jones, Assistant Director
Registration and Health Evaluation Division **HSM-01005**

Doug Okumura, Assistant Director
Enforcement and Environmental Monitoring Division

FROM: Paul H. Gosselin (Original signed by PG)
Acting Chief Deputy Director
(916) 445-4330

DATE: January 10, 2001

SUBJECT: DEPARTMENT POLICY ON THE RISK MANAGEMENT AND
MITIGATION PROCESS

This memorandum and the attached document establish a written policy regarding the process used by the Department of Pesticide Regulation to develop and implement mitigation strategies for pesticides with unacceptable human exposures.

Please review the attached risk management and mitigation process document, and discuss it with your Branch Chiefs. I recommend we use this process for future risk characterization documents that have unacceptable margins of exposure.

I would like to thank the Branch Chiefs for developing a process that uses a coordinated departmental effort to develop mitigation strategies. This process also keeps internal and external stakeholders informed of our regulatory intent, and provides them with an opportunity to comment.

If you have any questions, please contact me.

Attachment

cc: Paul Helliker (w/Attachment)
Chuck Andrews (w/Attachment)
Barry Cortez (w/Attachment)
David Duncan (w/Attachment)
Dr. Gary Patterson (w/Attachment)
Dr. John Sanders (w/Attachment)



Risk Management & Mitigation Process

January 10, 2001

The Director and/or Chief Deputy Director are responsible for making a risk management decision after the risk characterization document (RCD) is completed. This document describes the Department of Pesticide Regulation's process to develop and implement mitigation strategies for pesticides with unacceptable human exposures.

Risk Management Decision

Step One:

A RCD with acceptable margins of exposure (MOE) does not require additional mitigation measures to be developed. If the completed RCD contains MOEs that may be unacceptable, the Assistant Director, Registration & Health Evaluation Division, forwards a copy of the completed RCD and a cover memorandum with recommendations to the Chief Deputy Director. The cover memorandum includes the following information:

1. A summary of the risk and exposure appraisal findings with risk management recommendations;
2. An update on the U.S. EPA registration status, including the federal risk assessment (e.g., special review, Re-registration Eligibility Document) and any mitigation proposals under consideration, since the RCD was finalized (prepared by the Medical Toxicology Branch);
3. A summary of any changes in the California pesticide registration status, including label amendments or new product registrations that occurred after the RCD was finalized (prepared by the Pesticide Registration Branch); and
4. Recommendations for mitigating unacceptable risks.

Step Two:

The Director or Chief Deputy Director provides a written Risk Management Directive to the Assistant Director of Registration & Health Evaluation. Copies are also provided to the Pesticide Registration, Worker Health and Safety (WH&S), Medical Toxicology, Pesticide Enforcement, and Environmental Monitoring & Pest Management (EM&PM) Branches. The Directive indicates the exposure scenarios and unacceptable MOEs that require mitigation, or other actions (e.g., coordinate a mitigation proposal with U.S. EPA) that should be taken. The Director or Chief Deputy Director should also indicate his or her reasoning for the decision. If necessary, the Assistant Director of Registration & Health Evaluation schedules a meeting with the Director and/or Chief Deputy Director to discuss the Risk Management Directive.

Mitigation Development

Step One:

Upon receipt of the Risk Management Directive, the Pesticide Registration Branch prepares a notice informing all registrants and other interested parties (e.g., Office of Environmental Health Hazards Assessment, Department of Food and Agriculture, commodity groups, worker advocates, county agricultural commissioners, pest control applicator organizations) of the exposure scenarios and unacceptable MOEs that require mitigation. The Registration Branch sends a copy of the notice to DPR Branch Chiefs. The notice will give the registrants 30 days to submit proposed mitigation measures to DPR. Interested parties will not be asked to comment.

Step Two:

If a registrant submits proposed mitigation measures, the WH&S Branch reviews it to determine whether the exposure scenarios and unacceptable MOEs are addressed. If necessary, the Assistant Director of Registration & Health Evaluation schedules a meeting with the Director and/or Chief Deputy Director to discuss the registrant's proposal. Appropriate Branch Chiefs and staff will be invited to attend the meeting.

Step Three:

If the registrant's proposal was unacceptable, the WH&S Branch Chief assigns a principle author to develop a draft Mitigation Document. The author of the Exposure Assessment Document (EAD) will normally be assigned to develop the draft Document.

(Note: The principle author works with a team of other WH&S Branch scientists to complete the assignment.)

The WH&S Branch principle author reviews the completed RCD and the Assistant Director's memorandum (see Risk Management, Step One) and determines whether the pesticide sales and use report data, and pesticide illness and injury information should be updated. If an update is needed, request a query from the appropriate Branch. The WH&S Branch principle author updates the above information in the draft Mitigation Document.

(Note: Pesticide sales, use and illness data gaps greater than one year old should be updated.)

Step Four:

The WH&S Branch principle author develops a draft Mitigation Document for the exposure scenarios identified in the Risk Management Directive. The proposal includes exposure scenarios requiring mitigation, the corresponding unacceptable MOEs from the RCD, proposed mitigation measures for each scenario, and modified MOEs after mitigation. The draft Mitigation Document is reviewed and approved by the WH&S Branch Senior Toxicologist.

Step Five:

The WH&S Branch Chief sends the Risk Management Directive, draft Mitigation Document, and the registrant's mitigation proposal (if submitted) to the Pesticide Registration, Medical Toxicology, Pesticide Enforcement and EM&PM Branches for review prior to scheduling a Mitigation Scoping meeting.

Internal Mitigation Scoping Meeting: The WH&S Branch Chief schedules a meeting with representatives from Pesticide Registration, Medical Toxicology, Pesticide Enforcement and EM&PM Branches to discuss the draft Mitigation Document and other related information. The WH&S Branch obtains input from the Branch representatives on the draft Mitigation Document. The WH&S Branch Chief may determine that further meetings are necessary to discuss the draft Document.

The Pesticide Registration, Medical Toxicology, Pesticide Enforcement and/or EM&PM Branch notify the WH&S Branch Chief in writing if the draft Mitigation Document cannot be implemented. The notification should include justification for the recommendation.

Step Six:

External Mitigation Scoping Meeting: The WH&S Branch Chief schedules meetings with Branch representatives, registrants and interested parties (e.g., OEHHA, CDFA, commodity groups, worker advocates, county agricultural commissioners, pest control applicator organizations) to discuss the draft Mitigation Document and other related information. The WH&S Branch obtains input from registrants and interested parties on the draft Document.

Step Seven:

After input is received from Branch representatives, registrants and interested parties, the WH&S Branch principle author finalizes the draft Mitigation Document. The document includes updated pesticide sales and use data (if needed), an introduction, margins of exposure under current label directions (e.g., personal protective equipment, label rates, crops), margins of exposure following mitigation, summary of mitigation recommendations, a copy of the Risk Management Directive, and references.

The document is reviewed by the WH&S Branch Senior Toxicologist and sent to the Peer Review Manager for processing.

Step Eight:

After the WH&S Branch Chief approves the draft Mitigation Document, the final draft Document is forwarded via memorandum to the Assistant Director, Registration & Health Evaluation Division, and Chief Deputy Director for review and approval.

If requested, the WH&S Branch Chief, Senior Toxicologist, and the principal RMD author attends a briefing with the Assistant Director and Chief Deputy Director.

After the Chief Deputy Director signs off on the memorandum approving the Mitigation Document, it can be released to the public. WH&S Branch forwards a copy of the completed Mitigation Document (i.e., HS Report) to the Pesticide Registration, Pesticide Enforcement, EM&PM and Medical Toxicology Branches. The Pesticide Registration Branch sends the copies of the completed Document to all registrants and interested parties (e.g., OEHHA, CDFA, commodity groups, worker advocates, county agricultural commissioners, and pest control applicator organizations). The document will be posted on the DPR public web site and released to the public.

Step Nine:

The WH&S Branch informs U.S. EPA and OEHHA of DPR's intent to implement mitigation measures identified in the completed Mitigation Document.

Mitigation Implementation

The Chief Deputy Director assigns the appropriate Assistant Director to coordinate the implementation of RMD. The following mitigation strategies will be considered:

1. Adopt interim mitigation measures by issuing Suggested Permit Conditions.
 - a. In consultation with the WH&S Branch, the Pesticide Enforcement Branch drafts the permit conditions and may conduct the following activities:
 - b. Obtains input from Enforcement Regional Offices and/or CAC.
 - c. Notifies interested parties (e.g., commodity groups, worker advocates, registrants, and pest control applicator organizations) to obtain input on the suggested permit conditions.

- d. Develops a final draft proposal for review by appropriate DPR staff. Issues an Enforcement Letter as DPR policy with the attached Suggested Permit Conditions.
 - e. Explores the need for, and develops as appropriate, a Frequently Asked Questions (FAQ) letter to be issued with the Enforcement Letter, or to follow later.
 - f. Develops training, if necessary, for DPR, CAC, and others. If there are registrant-provided training or outreach presentations for the implementation, Pesticide Enforcement staff may assist in developing/reviewing the education and/or auditing those activities.
2. Establish interim mitigation measures by adopting Emergency Regulations.
 - a. In consultation with the WH&S Branch, the Pesticide Enforcement Branch staff coordinates with the Office of Policy Coordination and Continuous Improvement (OPCCI) in developing appropriate regulatory language. Review and implementation of the regulations may involve many of the steps identified in #1. above.
 - b. The WH&S Branch Chief schedules a meeting with OEHHA to discuss the proposed emergency regulation and supporting documentation (e.g. RCD, RMD). DPR considers OEHHA's comments when finalizing the emergency regulation.
3. Adopt the RMD through Pesticide Label Changes.
 - a. If the registrant(s) agrees to voluntarily amend the label(s) of a pesticide product(s), the registrant(s) must submit a draft, amended label(s) to the Pesticide Registration Branch. The Pesticide Registration Branch routes the draft, amended label(s) to the WH&S and Pesticide Enforcement Branches for review.
 - b. The Pesticide Registration Branch contacts interested parties (e.g., commodity groups, worker advocates, county agricultural commissioners, and pest control applicator organizations) to inform them that a meeting can be requested to discuss label amendments being considered by DPR.
 - c. After the draft, amended label(s) is accepted by DPR, the Pesticide Registration Branch will notify the registrant(s) that label amendments can be submitted to U.S. EPA. DPR may also submit the label amendments to U.S. EPA for the registrant.
 - d. The Pesticide Registration Branch contacts interested parties (e.g., commodity groups, worker advocates, county agricultural commissioners, and pest control applicator organizations) to inform them that label amendments were accepted by DPR.

- e. Upon receipt of the U.S. EPA stamped approved label(s) and letter of acceptance, the Pesticide Registration Branch will process the requested label amendments.
4. Establish the RMD by adopting Pesticide Regulations.
- a. In consultation with the WH&S Branch, the Pesticide Enforcement Branch staff coordinates with OPCCI in developing appropriate regulatory language. Review and implementation of the regulations may involve many of the steps identified in #1. above.
 - b. For regulations dealing with worker safety, the WH&S Branch Chief schedules a meeting with OEHHHA to discuss the proposed regulation and supporting documentation (e.g. RCD, RMD). DPR coordinates with OEHHHA to develop the regulatory language and obtain input on the proposal.
5. Cancellation of the Pesticide Product(s).
- a. The Pesticide Registration, Medical Toxicology and WH&S Branches forward all relevant documents, reports, memoranda and letters to the Assistant Director of Registration and Health Evaluation.
 - b. The Assistant Director of Registration and Health Evaluation prepares a memorandum with supporting documentation requesting cancellation to DPR Legal Counsel.
 - c. The Chief Deputy Director contacts interested parties (e.g., commodity groups, worker advocates, county agricultural commissioners, and pest control applicator organizations) to inform them of the cancellation action under consideration. Branch Chiefs will also receive notification that interested parties were contacted.
 - d. DPR Legal Counsel prepares the cancellation order and carries out all subsequent steps in the cancellation process.